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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,301	07/27/2001	Roberto A. Macina	DEX-0188	8552

26259 7590 05/10/2005

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EXAMINER
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HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/806,301

Applicant(s)

MACINA, ROBERTO A.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 11-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 11-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The amendment filed November 22, 2004 is acknowledged. Claims 11-24 were added. Claims 1 and 11-24 are pending and examined on the merits.
2. However, in view of a new rejection over the prior art, the finality of the previous Office action is withdrawn and prosecution on the merits continues.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***New Grounds of Rejection:***

4. Claims 1 and 11-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11-24 are indefinite because the steps of the claimed methods do not appear to correlate with the stated purpose of the preamble. In the preamble, the purpose of the method is the detection of prostate cancer, ovarian cancer or uterine cancer. However, the steps of the method include the measurement of levels of ESBPII polypeptide in *any* cell type, *any* tissue type and in *any* bodily fluid. The lack of correlation between the stated purpose of the preamble and the method steps occurs because, as discussed in previous Office actions, levels of ESBPII polypeptide appear to be correlated with the diagnosis of breast cancer. Thus, it is not clear how the claimed methods are distinguished from a method for diagnosis of breast cancer, when the

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active steps are considered, because there is no limitation of cell type or tissue type.

Furthermore, because bodily fluids such as blood, plasma or serum receive input from the entire body it is not clear how measuring ESBPII polypeptide levels found in bodily fluids allows one to distinguish between different types of cancer. Therefore, because the cell or tissue to be tested may be any cell or tissue, and because bodily fluids derived from all parts of the body, it is not clear how the claimed inventions, comprising measuring levels of ESBPII polypeptides in any cell, any tissue and bodily fluids, are different from a method for diagnosis of breast cancer. For these reasons the scope of the claims is in question.

5. Claims 1, 11-13, 16, 17, 20, 21 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated over Lehrer (Lehrer et al, U.S. Pub. NO.: US 2002/0034739).

The claimed inventions are drawn to methods for detecting the presence of prostate, uterine or ovarian cancer in a patient, comprising measuring levels of ESBPII polypeptide encoded by SEQ ID NO: 1 or comprising SEQ ID NO: 2; and comparing the measured levels of the polypeptide with levels of the polypeptide in cells, tissues or bodily fluids from a normal human control, wherein an increase in measured levels of the polypeptide in the patient versus the normal human control is associated with the presence of prostate, uterine or ovarian cancer. Because the claims are drawn to methods where the measurements are made in bodily fluids, the claimed methods read on detection of metastasis of prostate, uterine or ovarian cancer. Furthermore, it is not clear, as indicated above in the rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, how any one cancer may be diagnosed if a measurement is made in samples of bodily fluids.

Lehrer teaches methods of detection of metastasis of prostate, uterine or ovarian cancer comprising the detection of Lipophilin B polypeptide (the same as ESBPII polypeptide) in bodily fluids such as blood (paragraph 0029 and 0032). Therefore, because the claimed methods read on methods of detection of metastasis, Lehrer teaches methods that are the same as that claimed.

The following rejection is reinstated:

6. Claims 1, 11-13, 16, 17, 20, 21 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Billing-Medel (U.S. Patent 6,183,952; issued Feb. 6, 2001; filing date Aug. 15, 1997; of record). The claimed inventions are drawn to methods for detecting the presence of prostate, uterine or ovarian cancer in a patient, comprising measuring levels of ESBPII polypeptide encoded by SEQ ID NO: 1 or comprising SEQ ID NO: 2; and comparing the measured levels of the polypeptide with levels of the polypeptide in cells, tissues or bodily fluids from a normal human control, wherein an increase in measured levels of the polypeptide in the patient versus the normal human control is associated with the presence of prostate, uterine or ovarian cancer. Because the claims are drawn to methods where the measurements are made in bodily fluids, or in any cell or tissue type, it is not clear how one distinguishes the measurement of breast cancer from any other cancer. Therefore, the claims appear to read on methods that are the same as those of detecting breast cancer.

Billing-Medel teaches methods for diagnosing the presence of breast cancer, comprising measuring a protein having the sequence of SEQ ID NO: 2 (referred to as BU101) (see col. 60, lines 7-9, col. 6, lines 12-35, col. 7, lines 48-61 and col. 64, lines 1-14). Thus, Billing-Medel teaches methods that are the same as that claimed.

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***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833.

Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran

Patent Examiner

May 3, 2005



**ALANA M. HARRIS, PH.D.**

**PRIMARY EXAMINER**